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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,783	02/20/2004	Alan R. Klenk	MVMDINC.060A	6668

20995 7590 03/24/2008
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EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

NOTIFICATION DATE	DELIVERY MODE
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03/24/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No. 10/783,783	Applicant(s) KLENK ET AL.	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17-25 and 27-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17-25 and 27-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/02/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/02/2008 has been entered.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 01/02/2008 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-10, 20-25, and 27-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Ginn** (U.S. Pub. No. **2003/0050665**) in view of **Johnson** (U.S. Patent No. **6,485,504**).

Claims 1-10, 20-25, and 31-35: Ginn discloses delivering an elongate body delivered through an outer catheter **152** having a proximal end and a distal end to the patent foramen ovale, the elongate body having a tissue piercing structure **116** at its distal end, a coil ("filament") **130**, and an opening **122** near its distal end, advancing the tissue piercing structure and the coil relative to a loading portion or collar **154** coil through the septa of the of the patent foramen ovale, wherein both the tissue piercing structure and the coil extend into the septum primum first and then the septum secundum (page 4, paragraphs 47-48), the loading collar **154** having a slot for releasably engaging a proximal end of the coil (page 6, paragraph 0071 and page 7, paragraph 73), the elongate body being rotatable and axially slidable relative to the loading collar, and withdrawing the tissue piercing structure from the septa of the patent foramen ovale, wherein the coil when released contracts to pinch the septum primum and septum secundum together (Figures 6-8B and page 6, paragraphs 63-64).

Ginn discloses the claimed invention except for the distal end of the coil being releasably engaged with the opening in the elongate body and releasing the distal end of the coil from the elongate body, in order to axially elongate and radially reduce the coil, as well as retracting the tissue piercing structure (or elongate body) from the septum primum and septum secundum to allow the distal end of the coil to exit the opening of the tissue piercing structure and rotating the loading collar to allow the proximal end of the coil to disengage from the loading collar.

Johnson teaches a method of closure for hard or soft tissue including a coil ("grommet") **100** having a distal end that is releasably engaged with an opening **116** of an elongate body **108**, and releasing the distal end of the coil from the elongate body in order to axially elongate and radially reduce the coil by retracting the elongate body from the tissue to allow the distal end of the coil to exit the opening of the elongate body and rotating the loading collar **120** to allow the proximal end of the coil to disengage from the loading collar (Figures 24-26). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Ginn by having the distal end of the coil be releasably engaged to the elongate body, as taught by Johnson, in order to effectively narrow the coil in diameter to facilitate deployment and also to minimize damage to tissue and allow flexibility and movement by the patient without disturbing the healing process (col. 1, lines 32-36 and col. 19, lines 9-32).

Claims 27-30: Ginn discloses the coil having a tang (**133** on the distal end and **132** on the proximal end) that extends into a diameter defined by the coil which is sized to extend through a septum primum and a septum secundum of a patent foramen ovale

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(Figures 6-8B). Although a plurality of coils on the loading portion is not disclosed, it would have been obvious of one of ordinary skill in the art to modify the loading portion of Ginn to accommodate multiple coils in order to further secure the septum primum and septum secundum together.

5. Claims 11-15 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Ginn** (U.S. Pub. No. **2003/0050665**) in view of **Johnson** (U.S. Patent No. **6,485,504**), as applied to claim 1 above, and further in view of **Pierson, III** (hereinafter "**Pierson**") (U.S. Patent No. **6,663,633**).

Claims 11-14: Ginn and Johnson disclose the claimed invention except for advancing a second coil releasably engaged with the elongate body through the septa of the patent foramen ovale at a location adjacent to the first coil and releasing the second coil from the elongate body, wherein the second coil when released contracts to pinch the septum primum and the septum secundum.

Pierson teaches releasably engaging a first coil **12** and an adjacent second coil **12'**, or a plurality of discrete implantable coils, from a single delivery device having a tissue piercing structure **40** in order to draw two ends of tissue **90** together (Figures 1A-1E and col. 8, lines 12-16). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a second coil in the delivery member to the septa of the patent foramen ovale, as taught by Pierson, to Ginn and Johnson in order to provide a more secure closure by covering more surface area of the tissue.

Claims 15 and 17-19: Ginn, Johnson, and Pierson do not expressly disclose the

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plurality of coils being each advanced first through the septum primum and then through the septum secundum, wherein each of the coils after being advanced through the septa of the patent foramen ovale has a first end in the septum primum or left atrium and a second end in the septum secundum or right atrium, or having advancing three coils through the septa. However, it would have been obvious to one of ordinary skill in the art to modify the combined invention of Ginn, Johnson and Piercon by providing any number of fasteners that cover more surface area to strengthen the binding force and closure of tissue, as well as applying the coils in whichever fashion that would most benefit the patient's septal defect, which is well known in the art.

Response to Arguments

6. Applicant's arguments with respect to claims 1-15, 17-25, and 27-35 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/

Examiner, Art Unit 3734

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731